REMARKS

Claims 53, 57, 59, 60, 63-70 and 72-80 are pending. Claims 53, 57-60, 63-64 and 72-80 are rejected under 35 U.S.C. §112, first paragraph. Claims 68-70 are rejected under 35 U.S.C. §102 (b) and claims 65-67 are rejected under 35 U.S.C. §103. For reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

1. The Rejections Under 35 U.S.C. § 112, ¶ 1 Should Be Withdrawn

The Examiner has rejected claims 53, 57-60, 63-64 and 72-80 under 35 U.S.C. §112, first paragraph, because the specification while enabling for a method for inhibiting plant fungal growth *in vitro* or inhibiting mutagenesis in a microorganism via administration of an organic solvent extract of *Aristolochia taliscana*, does not reasonably provide enablement for a method of inhibiting mutagenesis or fungal growth in any organism such as mammals.

In particular, the Examiner alleges "that the claims remain broad enough to to cover any mutagenesis (*i.e.*, cancer caused by DNA mutations)." Further, the Examiner alleges that " although it is accepted that certain substances which have been shown to inhibit mutagenesis via Ames testing have actually shown some positive results *in vitro*, or *in vivo* with mice and rats, this does not provide a clear nexus between Ames testing and *in vivo* or even *in vitro* results, especially with regard to mutagenesis which is difficult and rare to treat such as cancer."

Applicant respectfully submits that this rejection is in error for the following reasons. First, mutagenesis is a process by which nucleic acid molecules are damaged by exposure to reagents such as chemicals or ultra violet radiation. Mutagenesis is not a disease which is subject to treatment, but rather, a process that may lead to diseases such as cancer. Applicant maintains

that the claims of the present invention encompass a method of ***inhibiting mutagenesis***, not a method for treating a disease resulting from mutagenesis as suggested by the Examiner in his rejection (see above).

Second, Applicant has established by the submission of over six different references that the Ames test is a widely accepted means of establishing mutagenicity of various compounds ***and*** that the Ames test is used as a means to predict *in vivo* mutagenic/carcinogenic activity (see Exhibits 1-6, of Applicant's response filed March 10, 2003). If it is the Examiner's contention that the Ames test is *not accepted* as a means of establishing mutagenicity and predicting *in vivo* mutagenic activity, then, Applicant respectfully request support for that contention.

Third, the ability of *Aristolochia taliscana* extracts to inhibit the mutagenesis of any given compound can be easily tested using the Ames test, followed by routine animal testing to verify *in vivo* activity. Such testing would be routine and would not require undue experimentation. Therefore, the claimed invention is enabled.

With regard to inhibition of fungal growth, the Examiner maintains that a method for inhibiting plant fungal growth *in vitro* does not reasonably provide enablement for a method of inhibiting fungal growth in organisms such as mammals.

Applicant asserted in his response filed March 10, 2003, that although the specification only disclosed the use of plant fungus species, it would be routine to substitute fungal species that infect mammals, such as *Candida albicans, Aspergillis fumigatus*, *Trichophyton mentagrophytes* and *Cryptoccocus neoformans,* and that such substitutions would not require undue experimentation. Furthermore, it was asserted that assays for determining antifungal activity, such as that disclosed in Example 5, are simple and well within the knowledge of one of skill in the art. Thus, the specification provides adequate support for enabling the presently

claimed method of inhibiting fungal growth in a substrate.

In his response, the Examiner noted that Applicant's arguments "were fully considered but not found persuasive." However, the Examiner failed to state his reasons for remaining unpursuaded. Applicant respectfully requests that the Examiner state his reasons for believing that it would not be considered routine to substitute mammalian fungi for plant fungi, so that Applicant may properly respond to the rejection.

The Rejections Under 35 U.S.C. § 102(b) Rejections Should Be Withdrawn

The Examiner has rejected claims 68-70 under 35 U.S.C. §102 (b) as being anticipated by de la Parra *et al.* (US 4782077;"de la Parra"). The Examiner alleges that the claimed composition employs the same process steps as the cited art and concludes that the composition inherently anticipates the present invention.

For a claim to be anticipated by a reference, "there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Gannett, Inc.*, 927 F.2d 1565 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Moreover, a claim is anticipated and fails to meet the requirement of §102 only when a single prior art reference discloses each and every element of the claimed invention. *Lewmar Marine, Inc. v. Barient*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), emphasis added.

Applicant asserts that claims 68-70 of the present invention encompass pharmaceutical compositions comprising an extract derived from *Aristolochia* wherein the extract "contains at least 25% by weight of a phenolic eupomatenoid compound, at least 8% of Licarin-A and at least 8% by weight of a non-phenolic eupomatenoid." In contrast, de la Parra merely discloses a

method for purification of *taliscanin*, not eupomatenoids or licarin-A, from *Aristolochia*. Said method comprises extraction *followed by alumina chromatography to derive fractions containing purified taliscanin.*

Given the difference between the claimed compositions and the composition disclosed by de la Parra, the claims cannot be anticipated.

The Rejections Under 35 U.S.C. §103 Rejections Should Be Withdrawn

Claims 65-67 are rejected under 35 U.S.C. §103 as being unpatentable over de la Parra *et al.* (US 4782077).

A finding of obviousness under §103 requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere* 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell* 853 F.2d 894, 903 (Fed. Cir. 1988).

The claims of the present invention relate to compositions comprising extracts derived from Aristolochia wherein said extracts comprise *eupomatenoids or licarin-A* capable of inhibiting fungal growth and mutagenesis. In contrast, de la Parra only discloses a method for purifiying taliscanin from *Aristolochia* wherein said method comprises extraction *followed by alumina chromatography to derive fractions containing purified taliscanin.* de la Parra fails to disclose, or even suggest, methods for purification of eupomatenoids or licarin-A from *Aristolochia.* Furthermore, given the differences in chemical structure between taliscanin and

eupomatenoids, one of skill in the art would not have had a reasonable expectation of success in purfying eupomatenoids having anti-fungal and anti-mutagenic activity from Aristolochia. Therefore the claimed invention cannot be rendered obvious.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicants believe that the invention described and defined by the amended claims is patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Respectfully submitted,

BAKER BOTTS, L.L.P.

By: Carmella L. Stephens

Rochelle K. Seide
Patent Office Reg. No. 32,300

Carmella L. Stephens
Patent Office Reg. No. 41,328

Attorneys for Applicants
30 Rockefeller Plaza
New York, NY 10112-4498
(212)408-2500